

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BERNARD BENE

Appeal No. 95-3830
Application 07/942,460¹

ON BRIEF

Before KRASS, JERRY SMITH and LEE, Administrative Patent Judges.
LEE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 12, 15-17, 20-22, 25 and 26 under 35 U.S.C. § 103 as being unpatentable over prior art. Claims 1-11 have been canceled. Dependent claims 13, 14, 18, 19, 23 and 24 have been indicated as being allowable if presented in proper form.

References Relied on by the Examiner

¹ Application for patent filed September 9, 1992.

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Shouldice et al.	U.S. Patent No. 4,897,184	Jan. 30, 1990
Lipps et al.	U.S. Patent No. 4,209,391	June 24, 1980
Veech	U.S. Patent No. 5,091,094	Feb. 25, 1992
Polaschegg (Polaschegg '053)	U.S. Patent No. 4,683,053	July 28, 1987
Polaschegg (Polaschegg '554)	U.S. Patent No. 5,100,554	March 31, 1992

The Rejections on Appeal

In the final Office action, claims 12-26 were rejected under 35 U.S.C. § 103 as being unpatentable over Shouldice et al., or Polaschegg '554, in view of Lipps et al., Veech, and Polaschegg '053. In the examiner's answer, the examiner withdrew the rejection of all claims over the combination of Polaschegg '554, Lipps et al., Veech and Polaschegg '053. Also in the examiner's answer, the examiner indicated that dependent claims 13, 14, 18, 19, 23 and 24 were allowable if rewritten in proper form.

Thus, before us in this appeal are only claims 12, 15-17, 20-22, 25 and 26. These claims stand rejected under 35 U.S.C. § 103 as being unpatentable over Shouldice et al., Lipps et al., Veech and Polaschegg '053.

The Invention

The invention is directed to an artificial kidney. The device measures a physicochemical characteristic of the fresh and

used dialysis liquid, computes a clearance value for a type of impurity based on the measured data, compares the calculated clearance with a predetermined clearance, and performs various control functions based on the results of the comparison.

Claim 12 concerns controlling a flow rate through the extracorporeal blood circuit. Claim 17 concerns controlling a flow rate through the dialysis liquid circuit. Claim 22 concerns controlling a blood filtrate exacting means on the basis of a duration of treatment calculated on the basis of the results of the comparison.

Representative claim 12 is reproduced below:

12. An artificial kidney comprising:

an exchanger having two compartments separated by a semipermeable membrane, a first compartment being connected to a circuit for extracorporeal circulation of blood having a circulating pump disposed therein, a second compartment being connected to a dialysis liquid circuit;

measurement means for measuring data corresponding to at least one physicochemical characteristic of a fresh dialysis liquid and at least one physicochemical characteristic of a used liquid;

computation means responsive to data received from the measurement means for calculating an actual clearance of the artificial kidney for a type of impurity; and

control means for controlling a flow rate through the extracorporeal blood circuit as a function of a comparison between the calculated clearance and a

predetermined clearance.

Opinion

We do not sustain the rejection of claims 12, 15-17, 20-22, 25 and 26. The teachings of Shouldice et al., Lipps et al., Veech and Polaschegg '053 would not have reasonably suggested the appellant's claimed invention.²

In the examiner's answer, the examiner explained in a meaningful manner, for the first time, his application of Shouldice et al. to the rejected claims. He further indicated (answer at 3 and at 4) that the secondary references Lipps et al., Veech and Polaschegg are cumulative with respect to the teachings of Shouldice et al.

In our view, there is error in the examiner's analysis. It concerns the requirement in all three independent claims 12, 17, and 22 for (1) a computation means responsive to data received from the measurement means "for calculating an actual clearance of the artificial kidney for a type of impurity," and for (2) a control means which performs a certain control function based on a comparison between the calculated clearance and a predetermined

² The appellant's supplemental reply brief (Paper No. 18) filed March 31, 1995, was not entered or considered by the examiner. Accordingly, we have not considered the supplemental reply brief.

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clearance.

The claimed invention requires a measurement means for measuring data corresponding to at least one physicochemical characteristic of a fresh dialysis liquid and at least one physicochemical characteristic of a used liquid. In that connection, the examiner found the following in Shouldice et al. (answer at 3):

Sensor 94 measures pressure of inlet dialyzate which **corresponds** to the physicochemical characteristic of the fresh dialyzate. Sensor 96 measures pressure of used liquid which **corresponds** to the physicochemical characteristic of dialysis containing the impurity "ultrafiltrate" from the blood. (Emphasis in original.)

Because the appellant has not specifically challenged or disputed the examiner's treating pressure as a physicochemical characteristic of a liquid, we will regard the measuring means feature as having been met by Shouldice et al.

What the appellant does argue is that the measured data on the dialysis liquid pressure would not permit a computation means to "calculate a clearance value for a type of impurity," and that Shouldice et al. further does not disclose any controlling function based on a comparison between the calculated clearance and a predetermined clearance for an impurity. We agree with the appellant.

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We can observe no basis for the examiner's finding (answer at 3) that:

The ultrafiltrate monitor (Fig. 2) uses the data from the [pressure] sensors to calculate the membrane clearance for ultrafiltrate impurity. The UF control 124 controls the flow rate as claimed. The ultrafiltrate rate is related to the transmembrane pressure.

Figure 2 of Shouldice et al. merely shows that data from pressure sensors 94 and 96 are inputted to the ultrafiltrate monitor 130. We find no discussion anywhere in Shouldice et al. concerning calculation of a clearance for "a type of impurity" based on the data from pressure sensors 94 and 96, and the examiner has cited none. The closest Shouldice et al. comes to that is the following (column 5, lines 9-13):

A TMP (transmembrane pressure) that is too high indicates that the operator is trying to pull too much ultrafiltrate (in which event he can lower the ultrafiltration rate) or that the membrane is clogged (in which event use of the clogged dialyzer must be discontinued).

Shouldice et al., in column 3, lines 13-14, defines the term "ultrafiltrate" as that liquid passing through the membrane in dialyzer 20 from blood to dialysate. Transmembrane pressure is not the same as either the fresh dialysis liquid pressure or the used dialysis liquid pressure as measured by pressure sensors 94 and 96. Even assuming that the transmembrane pressure can be

deduced from the fresh and used liquid pressure measured by sensors 94 and 96, the above-quoted text of Shouldice et al. merely suggests calculating the actual transmembrane pressure and then comparing it with a predetermined transmembrane pressure to see if it is too high.

Based on the foregoing, we find that the examiner has equated determining the general transmembrane pressure to calculating an actual clearance of the artificial kidney for a type of impurity. That is erroneous.

Consistent with the appellant's specification (see pages 14-15), regarding artificial kidneys the "clearance" for a type of impurity is based on the concentration of substances in the blood, on the flow rates of blood and the dialysis liquid in the exchanger, and on the membrane characteristics of the exchanger. It concerns the efficiency for removing the type of impurity. For instance, in the appellant's preferred embodiment (pages 14-15), conductivity of the dialysis liquid is measured, based on which the concentration of ionized substances, predominantly sodium, is calculated, and then through extrapolation and known rules of correspondence the "clearance" of urea is determined based in part on the characteristics of the exchanger and the flow rates of the blood and dialysis liquid. Alternatively, the

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disclosed invention calculates the actual "clearance" for creatinine (page 7).

In our view, it is unreasonable to regard transmembrane pressure in the exchanger, or either the input or output dialysis liquid pressure, as the claimed "clearance" for a type of impurity. The appellant is also correct that the clearance for a given type of impurity cannot be determined solely on the basis of detecting the pressure of fresh and used dialysis liquid. Pressure data alone, including the transmembrane pressure, cannot reveal how efficient a given type of impurity is being removed. The examiner has shown no evidentiary basis to find that Shouldice et al. discloses or reasonably suggests calculating the "clearance" for a type of impurity, and certainly not comparing the calculated clearance with a predetermined clearance as the basis for control. The statement in the examiner's answer that the claimed computation and control means are inherent in Shouldice et al. is without adequate support on this record.

Furthermore, it is also unreasonable, in the context of the appellants' claimed invention, to regard the entirety of the ultrafiltrate, i.e., that liquid passing in the exchanger from blood to the dialysate, as the "a type of impurity" contemplated by the claims. The ultrafiltrate contains all types of

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impurities as far as artificial kidneys are concerned and thus cannot satisfy claim features directed to calculating or performing something specific to "a type of impurity."

Alternatively, the examiner found (answer at 3) that "it would have been obvious to one with ordinary skill in the art, at the time the invention was made, to substitute conductivity meters for the pressure sensors of Shouldice et al. We disagree. The examiner has articulated no motivation for one with ordinary skill in the art to replace Shouldice et al.'s pressure sensors with conductivity meters. Conductivity meters do not measure pressure. The examiner also has not pointed to any useful purpose that would be recognized by one with ordinary skill in the art for having conductivity meters positioned upstream and downstream of the dialysis liquid in Shouldice et al. In any event, merely having the conductivity meters do not equate to or reasonably suggest calculating the actual "clearance for a type of impurity," comparing the calculated clearance with a predetermined clearance, and performing various control functions based on the results of the comparison.

Finally, with regard to claim 22, the examiner has not explained where in Shouldice et al. he finds that the duration of treatment has been calculated. Simply terminating operations

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when preset alarm limits have been exceeded is not the same as calculating a duration of treatment.

Lipps et al., Veech, and Polaschegg '053 do not, in any combination, make up for the above-noted deficiencies of Shouldice et al. The examiner is correct, insofar as the appellants' claimed invention is concerned, that these secondary references are merely cumulative to Shouldice et al. The examiner has not relied on these references to show the features of calculating an actual clearance for a type of impurity, comparing the calculated actual clearance with a predetermined clearance, and performing control functions based on the results of the comparison. We also do not find in these references, alone, or in combination, a reasonable suggestion for such features. In the final Office action, the examiner stated merely that Lipps et al. varies flow rates, Veech controls diffusion, and Polaschegg '053 shows a well known 3-way valve (Paper No. 9).

For the foregoing reasons, the rejection of claims 12, 15-17, 20-22, 25 and 26 over Shouldice et al., Lipps et al., Veech and Polaschegg '053 cannot be sustained.

Conclusion

The rejection of claims 12, 15-17, 20-22, 25 and 26 under 35 U.S.C. § 103 as being unpatentable over Shouldice et al.,

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Lipps et al., Veech and Polaschegg '053 is reversed.

REVERSED

ERROL A. KRASS)	
Administrative Patent Judge)	
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JERRY SMITH)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
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